
**United States Department of Agriculture
APHIS**



*BIOTECHNOLOGY PERMITS
ISO 9001:2000
QUALITY MANUAL*

April 17, 2008
Rev. 2

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Core

- C1 Receive and Review Applications
- C2a Conduct Preliminary Assessment of Notifications
- C2b Conduct Preliminary Assessment of Permits
- C3a Consult States - Notifications
- C3b Consult States - Permits
- C4a Finalize Assessment and Issue Notifications
- C4b Finalize Assessment and Issue Permits
- C5 Manage Requests for Information

Support

- S20 Establish and Maintain BRS Plans and Objectives
- S21 Provide Training and Knowledge
- S22 Manage Documents and Records
- S23 Collect and Analyze Performance Data
- S24 Conduct Reviews of the System Performance
- S25 Conduct Internal Audits
- S26 Manage and Resolve Customer Feedback
- S27 Maintain the ePermits System
- S28 Perform Corrective and Preventive Actions
- S29 Manage Nonconformity

Section 1 Overview

1.1 Introduction

The Plant Protection Act of 2000 prevents the introduction and spread of crop and environmental pests through agricultural quarantine and inspection programs. If allowed free entry, pest invertebrates, pathogens, or noxious weeds might establish and spread, causing many millions, if not billions, of dollars annually in damage. Native plants, including endangered species, might also be harmed.

The United States Department of Agriculture (USDA) issues permits to enable the introduction (importation, interstate movement, and environmental release) of certain genetically engineered (GE) organisms for education, research, and commerce. All regulated introductions of GE organisms must be authorized by APHIS under either its permitting or notification procedures. The BRS Permits Team and Environmental Risk Analysis Team carefully weigh risks and benefits when evaluating applications for permits and notifications. Permits expedite trade and provide information to importers to help prevent the invasion of plant pests. A lack or abuse of permits and notifications may allow pest infested materials to move into nurseries, farms, markets, or research institutions.

This Quality Manual documents the Quality Management System (QMS) that BRS designed to consistently provide products that meet customer/stakeholder requirements, fulfill regulatory requirements, and improve the quality of the organization's services. This Quality Manual establishes compliance with the ISO 9001:2000 Quality Management System Requirements and applies to:

Permits and Notifications for Genetically Modified Organisms

- Permit applications, using APHIS Form 2000/ePermits, provide details regarding the nature of the GE organism to be introduced and the conditions that will be used to prevent the spread and establishment of the organism in the environment.
- Notification applications are an administratively-streamlined alternative to the permit. The GE plant must meet specified eligibility criteria, and the introduction must meet certain pre-defined performance standards.

The Quality Manual describes the administrative processes that BRS uses to issue documents related to genetically engineered microorganisms. The Quality Manual documents our commitment to the following:

- Improve the quality of work.
- Maintain consistency in work processes.
- Describe current, acceptable processes for planning, conducting, evaluating and improving the work to produce permits and notifications for genetically modified plant propagules.
- Use for training, auditing, and reviewing work processes.
- Develop a continual process improvement platform.

1.2 Scope

The USDA – Animal and Plant Health Inspection Service (APHIS) – BRS based in Riverdale, Maryland, implements the coordination and administration of the review and issuance of notifications, permits, and information for genetically modified plants and microorganisms under Title 7 Code of Federal Regulations (CFR) Part 340.

Additional processes are outsourced to other parts of the U.S. Government:

- Issuing and Maintaining Scientific and Regulatory Guidance Documents – Other BRS Programs
- Facility Inspections – APHIS Inspectors
- Purchasing – APHIS Purchasing and Procurement
- Recruiting – APHIS Human Resources (HR)
- Maintaining the Computer Network – APHIS Information Technology
- Managing Information Security – APHIS Information Security

1.3 Application

BRS' quality management system satisfies the requirements of the ISO 9001: 2000 Standard. Due to the nature of BRS activities, product, and the scope of the QMS, the ISO 9001:2000 requirements that can not be applied will be considered for exclusion. The following ISO 9001:2000 requirements are excluded from compliance.

- 7.3 Design and Development. BRS Regulatory Operations Programs (ROP) and Environmental Risk Analysis Programs (ERAD) do not have design capabilities. Therefore clause 7.3 of the ISO 9001:2000 Standard does not apply to the QMS described by this manual.
- 7.4 Purchasing. BRS ROP and ERAD do not have purchasing facilities or functions. BRS uses the USDA-wide Purchasing Function to qualify vendors and issue purchase orders. Therefore clause 7.4 of the ISO 9001:2000 Standard does not apply to the QMS described by this manual.
- 7.5.2 Validation of Processes for Production and Service Provision. BRS ROP and ERAD operate service processes where product characteristics are transparent to interested parties and verifiable by BRS Regulatory Operations and the applicants. Therefore clause 7.5.2 of the ISO 9001:2000 Standard does not apply to the QMS described by this manual.
- 7.6 Control of Monitoring and Measuring Devices. BRS ROP and ERAD do not use measuring or monitoring devices to create its products that meet customer or regulatory requirements. Therefore, clause 7.6 from the ISO 9001:2000 Standard does not apply to the QMS described by this manual.

1.4 Organization

The relationship of BRS personnel who manage, perform, and verify work affecting quality is defined in Figure 1. BRS Permits and Environmental Risk Analysis Teams. Section 5.5.1 presents the details regarding responsibilities and authorities.

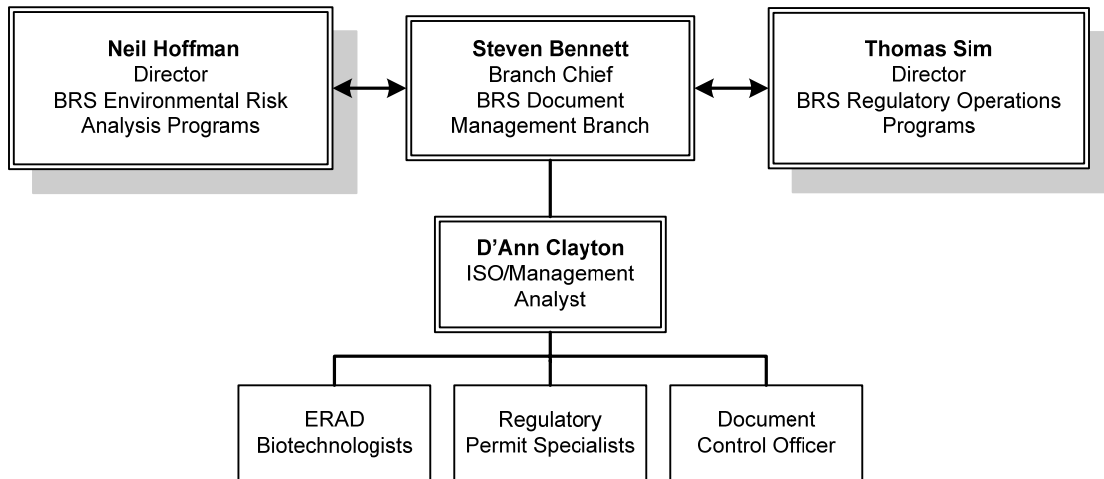


FIGURE 1. BRS Permits and Environmental Risk Analysis Teams

Section 2 Quality Policy

2.1 Policy Statement

BRS Regulatory Operations Managers initially approved the following Quality Policy on November 30, 2005 and revisited the Quality Policy on September 19, 2007. Copies of the Quality Policy are available in the Quality Management System Folder in the Document Warehouse on the I-drive network server.



QUALITY POLICY

We provide regulatory oversight and customer satisfaction through continual improvement.

Our commitment is to establish and meet objectives and other requirements that will protect American plant resources and provide our customers with permits, authorizations and information that meet their needs. To achieve this, we conduct our business in an environment of continual improvement. This means we use our QMS to:

- Provide training so we have the skills to meet our job responsibilities.
- Maintain documented procedures for our key processes so they remain transparent to us and the public.
- Control our key processes so they are effective and efficient in meeting our stated obligations.
- Measure important aspects of our key processes and take timely action to improve performance.
- Continually improve customer satisfaction and the effectiveness of our QMS.

Steven Bennett, Chief
Document Management Branch

Date: October 3, 2007

Section 3 Definitions and Acronyms

3.1 Definitions

Animal and Plant Health Inspection Service (APHIS): USDA Agency responsible for protecting and promoting U.S. agricultural health, administering the Animal Welfare Act, and carrying out wildlife damage management activities.

Biotechnology Regulatory Services (BRS): BRS implements the APHIS regulations for certain genetically engineered (GE) organisms that may pose a risk to plant health, in order to protect plant health. In the regulation of genetically engineered organisms, BRS is part of a science-based federal regulatory framework to protect America's agricultural resources and the broader environment.

Biotechnology Notifications: Documents issued by APHIS-BRS to allow a genetically modified plant material to move into the U.S., through the U.S., or between states. Materials eligible for this process are typically of lower risk as compared to regulated items that receive a permit. The types of notifications are described below.

Notification for Movement from State to State (Interstate Movement): Documents issued by APHIS-BRS to allow a genetically modified plant material to move within the U.S. from containment in one state to containment in another state. Regulation 7 CFR 340 requires this permit to be issued or denied within 10 days.

Notification for Import Movement: Documents issued by APHIS-BRS to allow a genetically modified plant material to move within the U.S. from containment in one state to containment in another state. Regulation 7 CFR 340 requires this permit to be issued or denied within 30 days.

Notification for a Release into the Environment: Documents issued by APHIS-BRS to allow genetically modified plant material to be released outside the constraints of physical confinement that are found in a laboratory, containment greenhouse fermented, or other contained structure. Regulation 7 CFR 340 requires this permit to be issued or denied within 30 days.

Notification for Interstate Movement and Release into the Environment: Documents issued by APHIS-BRS to allow genetically modified plant material to be released outside the constraints of physical confinement that are found in a laboratory, containment greenhouse fermented, or other contained structure. Regulation 7 CFR 340 requires this permit to be issued or denied within 30 days.

3.1 Definitions, cont.

Biotechnology Permit: Documents issued by APHIS-BRS to allow a single genetically modified plant material to move into the U.S., through the U.S, or between states. Types of permits are described below.

Interstate Movement Permit: Documents issued by APHIS-BRS to allow a single genetically modified plant material to move within the U.S. from containment in one state to containment in another state Regulation 7 CFR 340 requires this permit to be issued or denied within 60 days.

Import Permit: Documents issued by APHIS-BRS to allow a single genetically modified plant material to move from a foreign country to specific locations(s) within the United States. These locations must possess approved facilities capable of containing any risk. Regulation 7 CFR 340 requires this permit to be issued or denied within 60 days.

Release into the Environment Permit: Documents issued by APHIS-BRS to allow a single genetically modified plant material to be released outside the constraints of physical confinement that are found in a laboratory, containment greenhouse fermented, or other contained structure. Regulation 7 CFR 340 requires this permit to be issued or denied within 120 days.

Comprehensive Permit: A pilot project to allow a number of genetically modified plant materials to move under one permit. This project is not covered by ISO 9001:2000 certification.

CBI: Confidential Business Information. Information protected from disclosure under section 5 U.S.C. § 552(b)(4), of the Freedom of Information Act (FOIA). Includes `Trade Secrets`, and commercial and financial information for which substantial competitive harm could result if information was disclosed. Similar to SSI and SBU information.

Containment Facility: Prior to issuing a Permit for Import and/or Interstate Movement, BRS needs proof that the facility that will house the material is capable of containing it to prevent release into the environment. The Regulatory Specialist checks a database look-up table for evidence that the containment facility was inspected. If the facility has not been inspected, they notify the Compliance Branch. Compliance Branch then contacts the regional representative to arrange for an inspection of the facility. Inspected facilities may undergo periodic spot checks. Currently the inspection of Containment Facilities is not covered under ISO 9001:2000 registration.

3.1 Definitions, cont.

Endangered Species Act (ESA): Federal legislation intended to provide a means whereby the ecosystems upon which endangered and threatened species depend may be conserved, and provide programs for the conservation of those endangered species and threatened species, thus preventing extinction of native plants and animals.

ePermits: A secured web-based tool that provides customers with the ability to apply for a notification or permit, check the status of an application, and view the application online. ePermits also enables BRS and Federal regulatory officials to issue, track, and verify the validity of import permits, thus reducing data-entry, processing, delivery time, and expense.

Genetically Engineered Organism: The genetic modification of organisms by recombinant DNA techniques.

National Environmental Policy Act: The National Environmental Policy Act (NEPA) declares a national policy, which promotes efforts that prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man; to enrich the understanding of the ecological systems and natural resources important to the Nation; and to establish a Council on Environmental Quality. The NEPA process is intended to assist public officials in making decisions that are based on an understanding of environmental consequences. Establishes policy, sets goals, and provides means for carrying out the policy. Declares a national policy which will encourage productive and enjoyable harmony between man and his environment; to promote efforts which will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man; to enrich the understanding of the ecological systems and natural resources important to the Nation; and to establish a Council on Environmental Quality.

Organism: Any active, infective, or dormant stage or life form of an entity characterized as living, including vertebrate and invertebrate animals, plants, bacteria, fungi, mycoplasmas, mycoplasma-like organisms, as well as entities such as viroids, viruses, or any entity characterized as living, related to the foregoing.

Petition: Request for the deregulation of genetically modified plant material. This process is not included in ISO certification at this time (future enhancement).

Policy Statement: A declaration of a standard operating procedure.

Risk Assessment: The process of identifying hazards and evaluating the consequences and likelihood of specific hazards in qualitative or quantitative terms. This process should include estimates of uncertainty and should be objective, repeatable, and science-based.

3.1 Definitions, cont.

Stakeholder/Customer: A person or organization with valid interests in a given situation or action and who is affected, or can be affected, by the USDA's actions. The term applies to:

- Permit applicants (academic or commercial entity)
- USDA Field Officers (e.g., Plant Protection and Quarantine Officers)
- Cooperating local, State (e.g., State Plant Regulatory Officials) and Federal (e.g., Department of Homeland Security, Custom and Border Control) agencies
- The Biotechnology Industry
- BRS Employees

Territories or Possessions: These locations fall within USDA's regulatory authority; Guam, the Northern Mariana Islands, Puerto Rico, and the Virgin Islands of the United States.

7 CFR: The Code of Federal Regulations (CFR) is published in the Federal Register by the Executive departments and agencies of the Federal Government. Title 7 contains the regulations of the Department of Agriculture, Animal and Plant Health Inspection Service Parts 300 to 399 – Agriculture.

3.2 Acronyms

Acronym	Definition
APHIS	Animal and Plant Health Inspection Service
BRS	Biotechnology Regulatory Services
CAR	Corrective Action Request
CFR	Code of Federal Regulations
DCO	Document Control Officer
DHS	Department of Homeland Security
DMBC	Chief, BRS Document Management Branch
EPA	U.S. Environmental Protection Agency
ERAD	Environmental Risk Analysis Programs
ESA	Endangered Species Act
FDA	Food and Drug Administration
GE	Genetically Engineered
MRP	Marketing and Regulatory Programs
NEPA	National Environmental Policy Act
PAR	Preventive Action Request
PPQ	Plant Protection and Quarantine
QMS	Quality Management System
ROP	Regulatory Operations Programs
RPS	Regulatory Permits Specialist
SPHD	State Plant Health Director
SPRO	State Plant Regulatory Officials
USDA	United States Department of Agriculture

Section 4 Quality Management System

4.1 General Requirements

BRS established, documented, implemented, and maintains a Quality Management System in accordance with the ISO 9001:2000 Quality Management System Requirements and Standards, and U.S. regulatory policies and standards. BRS continually improves the effectiveness of its QMS by:

- a) Identifying the processes needed for its operations and the application of our processes throughout the organization;
- b) Determining the sequence and interaction of these primary processes;
- c) Determining criteria and methods needed to ensure that both the operation and management of these processes are effective;
- d) Ensuring the availability of resources and information necessary to support the operation and monitoring of these processes;
- e) Monitoring, measuring, and analyzing these processes; and
- f) Ensuring the implementation of actions necessary to achieve planned results and continual improvement of these processes.

The key processes within the BRS QMS include processes for management activities, provision of resources, product realization, and measurement and are presented in Figure 2 through Figure 4.

Figure 2. BRS Notification and Permit Quality Management System Process displays the processes for management activities, provision of resources, product realization, measurement and analysis, continual improvement, and additional processes needed for the QMS.

Figure 3. BRS Regulatory Operations – Sequence and Interaction of Key Processes presents the interactions of the ROP and ERAD key processes.

Figure 4. BRS ISO 9001:2000 Conformity Matrix displays cross-references between the BRS QMS processes and the requirements of the ISO 9001:2000 Standard.

Outsourced processes are controlled by subject matter professionals (with necessary clearance levels) using documented policies and procedures that comply with the regulations used by the BRS ROP and ERAD.

4.1.1 Processed-Based Quality Management System Model

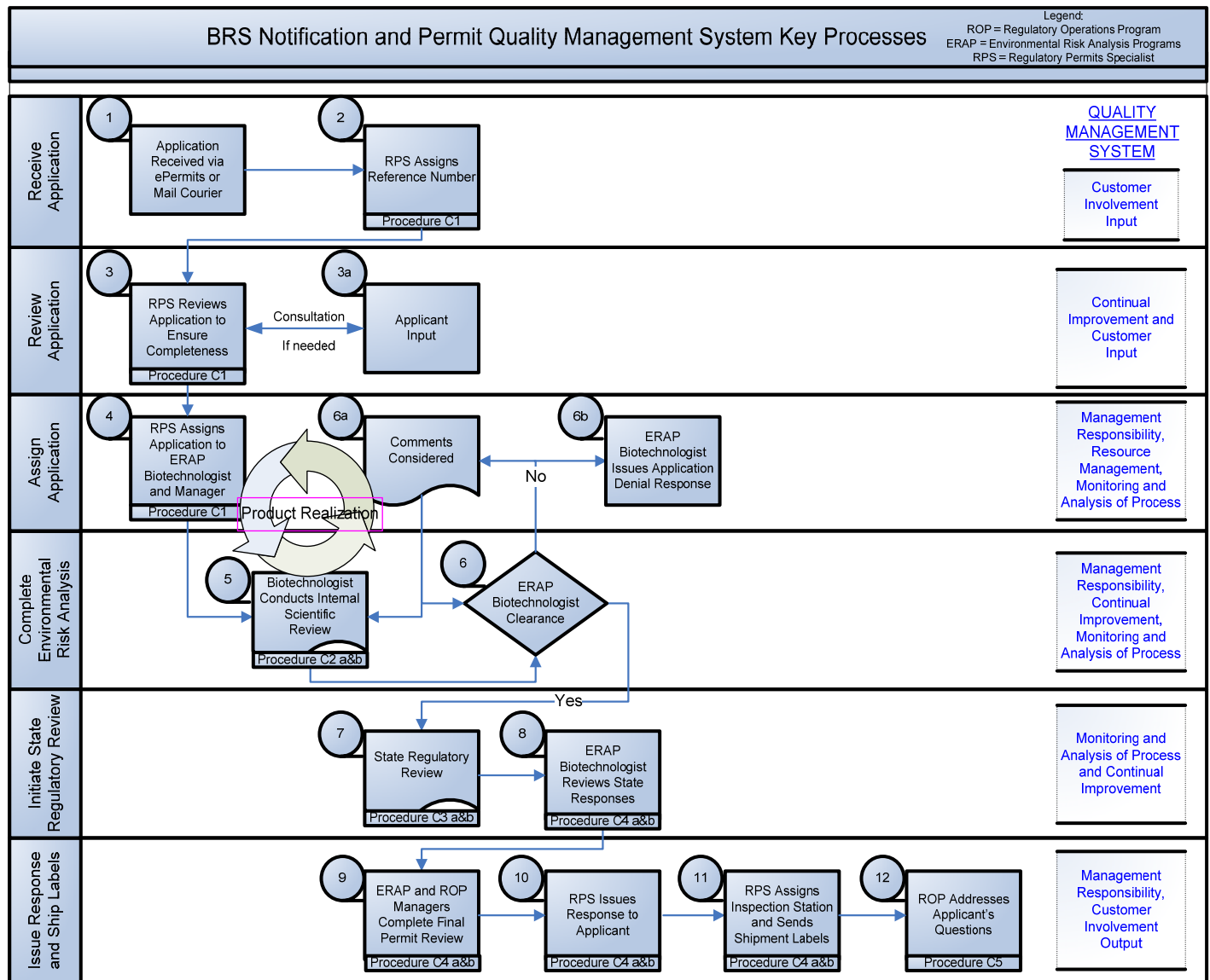


FIGURE 2. BRS Notification and Permit Quality Management System Key Processes

4.1.2 Sequence and Interaction of Key Processes Model

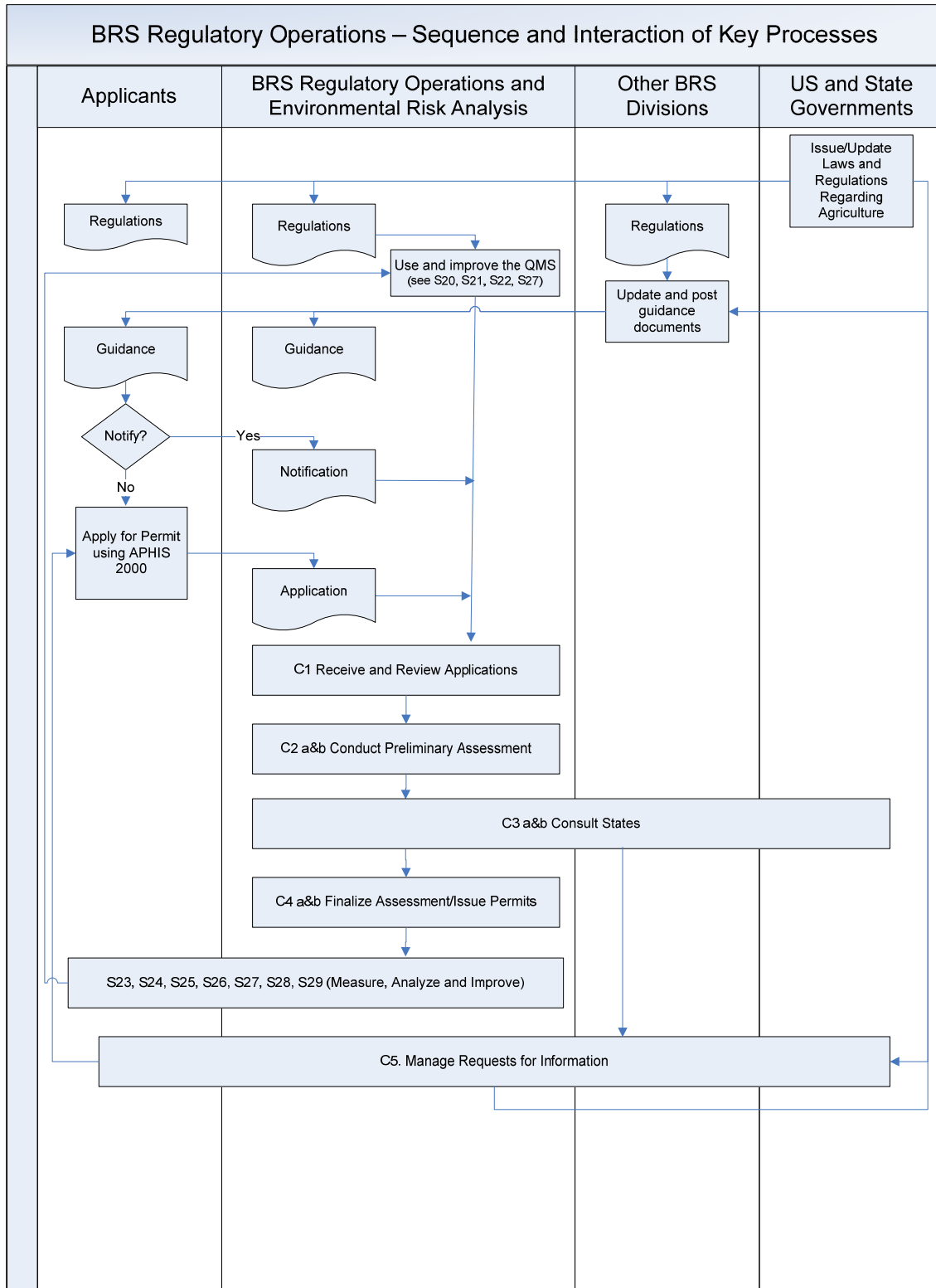


FIGURE 3. BRS Regulatory Operations – Sequence and Interaction of Key Processes

4.1.3 ISO 9001:2000 Conformity Matrix

BRS QMS Document Code = Contributing to ISO 9001:2000 conformity																																					
ELEMENT	Section 1	Section 2	Section 3	Section 4	Section 5	Section 6	Section 7	Section 8	SPARE	SPARE	C1	C2 a & b	C3 a & b	C4 a & b	C5	SPARE	SPARE	SPARE	SPARE	S20	S21	S22	S23	S24	S25	S26	S27	S28	S29	SPARE	SPARE	SPARE	SPARE	SPARE	SPARE		
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FIGURE 4. BRS ISO 9001:2000 Conformity Matrix

4.2 Documentation Requirements

4.2.1 General

The BRS QMS documentation includes:

- a) BRS' Quality Policy, which is documented in Section 2.1.
- b) BRS' Quality Objectives, which are documented in Section 5.4.
- c) This Biotechnology Permits ISO 9001:2000 Quality Manual.
- d) Documented procedures required by ISO 9001:2000, which include 4.2.3, Control of Documents; 4.2.4 Control of Records; 8.2.2 Internal Audit; 8.3, Control of Nonconforming Product; 8.5.2, Corrective Action; and 8.5.3, Preventive Action. Where the term documented procedures appears within this Quality Manual, the procedures are established, documented, implemented and maintained and may be in any specified format or type of medium.
- e) Documents needed by the organization (i.e., procedures, work instructions) to ensure the effective planning, operation and management of its processes.
- f) Records required by ISO 9001:2000, per Procedure S22 Manage Documents and Records.

The extent of the BRS QMS is based on:

- a) The size of the organization and type of activities.
- b) The complexity of processes and their interactions.
- c) The competence of personnel.

4.2.2 Quality Manual

This document is the Quality Manual for the BRS QMS. BRS has established and maintains this Quality Manual, which includes:

- a) The scope of the QMS, including details of and justification for any exclusion, per Section 1.2.
- b) Reference to the documented procedures established for the QMS. The relationship between the requirements of this Standard and the documented procedures is clearly shown, per Section 4.1.3.
- c) Description of the interaction between the processes of the QMS, per Sections 4.1.1 and 4.1.2.

The Distribution List documents all persons who received a controlled copy of the Quality Manual (Available via I-drive network server to all BRS personnel). The ISO/Management Analyst maintains the Distribution List (when applicable).

The Quality Manual becomes uncontrolled after printed from the I-drive network server.

4.2.3 Control of Documents

Documents required by the QMS are managed per Procedure S22 Manage Documents and Records including:

- a) Approve documents for adequacy prior to issue.
- b) Review and update as necessary and re-approve documents.
- c) Ensure that changes and the current revision status of documents are identified.
- d) Ensure that relevant versions of applicable documents are available at points of use.
- e) Ensure that documents remain legible and readily identifiable.
- f) Ensure that documents of external origin are identified and their distribution managed using the BRS Document Warehouse.
- g) Prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

The documents critical to the QMS are approved and controlled. These documents include the Quality Manual, Procedures, Work Instructions, Forms, and externally generated documents and records.

QMS documents are designated as approved when the DMBC's name appears in the approval section of the Revision History. The latest version of the controlled documents is available to all BRS employees on the I-drive network server. A printed copy of a QMS document is for reference use only and/or available upon request.

The Document Control Officer maintains a "Master List of Documents" which includes all internal and external documents used within the QMS.

4.2.4 Control of Records

The BRS QMS controls the records to provide evidence of conformity to requirements and the effective operation of the QMS. These records are collected, filed, and stored in a suitable environment to prevent damage, deterioration, or loss.

Procedure S22 Manage Documents and Records has been established to define the mechanisms needed for the identification, storage, protection, retrieval, retention time and disposition of records.

Section 5 Management Responsibility

5.1 Management Commitment

Management communicates its commitment to meeting customer/stakeholder, statutory, and regulatory requirements by:

- Establishing and communicating the Quality Policy and Quality Objectives to BRS.
- Conducting Management Reviews.
- Ensuring a provision of resources needed to attain objectives and customer satisfaction.

5.2 Customer (Stakeholder) Focus

The BRS Management Team ensures that customer/stakeholder requirements are defined and expectations are achieved with the goal of enhancing customer satisfaction, per Procedure S26 Manage and Resolve Customer Feedback.

5.3 Quality Policy

The Quality Policy, as documented in Section 2.1 of this manual, is reviewed by management for suitability and revised as necessary per Procedure S20 Establish and Maintain BRS Plans and Objectives.

5.4 Planning

5.4.1 Quality Objectives

The Management Team establishes and updates quality objectives using Procedure S20 Establish and Maintain BRS Plans and Objectives and Procedure S23 Collect and Analyze Performance Data.

Overall quality objectives are translated into performance standards and measures for processes, which are integrated into the process descriptions.

Changes to the quality objectives are planned using the S20 Establish and Maintain BRS Plans and Objectives process and are controlled and formalized through amendments in QMS documents using the process outlined in Procedure S22 Manage Documents and Records.

BRS' quality objectives include:

- Maintaining customer satisfaction of more than 3.5 (moving average basis).
- Complying with federally mandated timeframes to process permits and notifications.
- Ensuring zero non-complying permits or notifications.

5.4.2 Quality Management System Planning

The Management Team ensures that the planning of the QMS is completed in order to meet the requirements outlined in Section 4.1 of this Quality Manual and the quality objectives featured in Section 5.4.1 of the Quality Manual.

5.5 Responsibility, Authority, and Communication

5.5.1 Responsibility and Authority

The Management Team ensures that responsibilities, authorities, and competencies (i.e., corresponding abilities, skills, knowledge) of the personnel within the scope of the QMS are defined and communicated within the organization per the organizational chart, QMS procedures, and each position description maintained by APHIS HR.

Figure 1, in Section 1.4 of this manual, displays the organizational chart with positions of authority and responsibilities for all who manage and produce work results that affect quality.

The responsibilities and authorities are summarized below:

5.5.1 Responsibility and Authority cont.

Chief, BRS Document Management Branch (Management Representative): Manages and provides leadership in coordinating and consolidating matters pertaining to processing permits, processing environmental assessments, identification, processing risk assessments, and action decisions. Responsible for the overall implementation and continued compliance of the quality management system including:

- Conformity of QMS to ISO 9001:2000 with provision of advice and support to others relative to the quality management system.
- Oversight of Liaison with the external registrar.
- Oversight of the internal audit and document control processes that support continual improvement.
- Process Owner of the objective development and management review processes.
- Communicates with all Leadership regarding ISO related activities.

CAR/PAR Initiator: Any employee who determines that a Corrective Action Request (CAR) or Preventive Action Request (PAR) are required or should be implemented.

Director, BRS Regulatory Operations Programs: Supervisor; manages and provides leadership for the two branches within Regulatory Operations Programs. Responsible for the performance of the Division including:

- The overall achievement of quality objectives.

Document Control Officer: Responsible for the oversight of management of documents within the scope of the quality management system and the control of changes. Also assists with ongoing initiatives related to the QMS.

Management/ISO Analyst: Responsible for the effective day-to-day implementation of the processes that fall within the scope of the BRS quality management system.

- Ensures that process measurement data is collected, analyzed and those opportunities for improvement are identified and acted upon.
- Approves changes to processes.
- Responsible for providing support and expertise to Process Owners and others in BRS in areas relating to the use of statistical data and improvement activities.
- Tracks and monitors CARs and PARs to ensure corrective and preventive action requests are completed and verified for effectiveness before being closed out. Informs management of any barriers encountered in this process.

5.5.1 Responsibility and Authority cont.

Regulatory Permit Specialists: Provides customer and stakeholder service, reviews incoming applications and correspondence, and processes permits for previously documented regulated articles. Responsible for the processes and tasks as distributed per the procedure, which includes monitoring processes for effectiveness.

- Suggest changes using the formal change process.

Risk Assessment Scientists - Biotechnologist: Subject matter specialist who provides risk assessments for introduction of genetically engineered organisms for regulatory matters (notifications and permits). Responsible for the proper conduct of risk assessment tasks for which they have ownership.

- Suggest changes to the work methods using the formal change process.

5.5.2 Management Representative

BRS has appointed the Document Management Branch Chief as the Management Representative who is responsible for the following:

- Ensures the processes needed for the QMS are established, implemented, and maintained.
- Reports the performance of the QMS and needs for improvement to the Management Team.
- Ensures the awareness of customer requirements are promoted throughout BRS.

5.5.3 Internal Communication

Internal communication is accomplished via e-mail to employees, staff meetings, newsletters, and QMS employee orientation training.

5.6 Management Review

5.6.1 General

The BRS Management Team reviews the organization's QMS per Procedure S24 Conduct Reviews of System Performance. The Management Team conducts these reviews at least once a year to ensure continuing suitability and adequacy, discuss overall performance in achieving targets, and determine requirements to address gaps.

Records of management reviews are maintained per Procedure S22 Manage Documents and Records.

5.6.2 Review Input

The input to management review includes, but is not limited to:

- Results of audits.
- Customer and stakeholder feedback.
- Process performance and product conformity.
- Status of preventive and corrective actions.
- Follow-up actions from previous management reviews.
- Planned changes that could affect the QMS.
- Recommendations for improvement.
- Quality Policy and Quality Objectives.

5.6.3 Review Output

The output from management review includes decisions and actions related to:

- Improvement of the effectiveness of the QMS and its processes.
- Improvement of product related to customer and stakeholder requirements.
- Resource needs.

Section 6 Resource Management

6.1 Provision of Resources

BRS' Management Team plans and provides resources to implement and maintain the QMS, continually improve its effectiveness, and fulfill customer requirements per Procedures S20 Establish and Maintain BRS Plans and Objectives and S23 Collect and Analyze Performance Data. Plans identify the need for:

- Adequate personnel to conduct the activities identified in the BRS processes so that process performance requirements can be met.
- Appropriate organizational structure necessary to manage the processes.

6.2 Human Resources

6.2.1 General

Human Resources are allocated based on the overall establishment of BRS QMS Plans and Objectives. The Management Team ensures that personnel, who perform work that affects quality of product, are competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, Awareness, and Training

The Immediate Supervisors provide orientation to new employees and ensure that performance element standards are defined in employee performance plans to impart relevance and importance of an employee's activities to the organization's quality objectives per Procedure S21 Provide Training and Knowledge.

Employee Performance Reviews are conducted by the Immediate Supervisor twice a year and training needs are assessed to determine whether formal/on-the-job training will enhance product quality and customer satisfaction. Records of training are maintained in a staff member's personnel file located in the Immediate Supervisors' office.

6.3 Infrastructure and Work Environment

BRS is provided with needed workspace, services, and information technology as a part of the overall APHIS budgeting and provisioning process.

BRS Biotechnology Permitting uses special facilities for maintaining the security of intellectual property and other information that belongs to applicants for permits and notifications as outlined in Procedure S27 Maintain the ePermits System.

Section 7 Product Realization

7.1 Planning of Product Realization

BRS plans and develops the processes needed for product realization consistent with the requirements of the other processes of the QMS per Section 4.1 of this Quality Manual. In planning product realization, BRS determines the following, as appropriate:

- Quality objectives and requirements for the product.
- The need to establish processes, documents, and provide resources specific to the product.
- Required reviews and audits specific to the product.
- Records needed to provide evidence that the realization processes and resulting product fulfill requirements, per Procedure S22 Manage Documents and Records.

7.2 Customer (Stakeholder) – Related Processes

7.2.1 Determination of Requirements Related to the Product

Customers request BRS permitting services by accessing the APHIS ePermits web-based system to apply for a permit online, check the status of the application, view issued permits, and view other responses. The web-based system is designed to ensure that all the information, which is required to perform the service, is supplied by the customer or stakeholder.

7.2.2 Review Requirements Related to the Product

The customer and stakeholder requirements, as well as statutory and regulatory requirements, for services are reviewed to ensure that product requirements are adequately defined and BRS is equipped to fulfill the requirements.

Adequate records of stakeholder requirements and the outcome of the review are maintained.

Where product requirements are changed, BRS ensures that relevant documents are amended and relevant personnel are made aware of the changed requirements.

7.2.3 Customer (Stakeholder) Communication

BRS has determined and implemented effective arrangements for communicating with customers and stakeholders in relation to:

- Biotech Query (bioquery@aphis.usda.gov)
- Messaging (ePermits and Lotus Notes Exchanges)
- Customer and stakeholder feedback, including customer complaints per Procedure S26 Manage and Resolve Customer Feedback

7.3 Design and Development

This element does not apply to BRS ROP and ERAD. Justification: ROP and ERAD do not have design capabilities. In the event that BRS receives design capabilities, the ISO/Management Analyst is responsible for ensuring this element is addressed where necessary.

7.4 Purchasing

This element does not apply to BRS ROP and ERAD. Justification: ROP and ERAD do not have purchasing facilities/functions or products, which require purchased product inspections. This function is handled through other government agencies. In the event that BRS receives purchasing facilities or functions, the ISO/Management Analyst is responsible for ensuring this element is addressed.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

BRS plans and implements the procedures for delivery of services to ensure that they are completed in a controlled manner. Processes are fully developed in procedures, work instructions, and in supporting/reference documentation to facilitate process execution.

The procedures incorporate verification steps where required and are monitored to ensure that they are completed under controlled conditions.

If problems in delivery of service arise, customers (stakeholders) are encouraged to immediately report situations and prompt resolution is initiated per Procedure S26 Manage and Resolve Customer Feedback.

7.5.2 Validation of Processes for Production and Service Provision

This element does not apply to BRS ROP and ERAD. Justification: The changes to existing key processes are validated prior to use of product or service. In the event the current process changes, the ISO/Management Analyst is responsible for ensuring this element is addressed.

7.5.3 Identification and Traceability

Where appropriate, BRS identifies the product by suitable means throughout product realization. BRS identifies the product status with respect to monitoring and measurement requirements. Where traceability is a requirement, BRS controls and records the unique identification of the product as referenced in Section 4.2.4.

7.5 Production and Service Provision, cont.

7.5.4 Customer (Stakeholder) Property

BRS exercises care with Customer (Stakeholder) property while it is under the organization's control or being used by BRS. BRS identifies, verifies, protects, and safeguards Customer (Stakeholder) property provided for use or incorporation into the product.

If Customer (Stakeholder) property is lost, damaged, or unsuitable for use, the event is reported to the Customer (Stakeholder) and records are maintained.

Note: Customer (Stakeholder) property may include intellectual property and confidential business information.

7.5.5 Preservation of Product

BRS preserves the conformity of the product during internal processing and delivery to the intended destination by using appropriate resources (i.e., ePermits secured web-based system, Lotus Notes e-mail system, and the Document Warehouse data repository). Preservation includes identification, handling, packaging, storage, and protection. Preservation also applies to the constituent parts of a product.

7.6 Control of Measuring and Monitoring Devices

This element does not apply to BRS ROP and ERAD. Justification: ROP and ERAD do not have equipment or special tools to take measurements that verify the conformity of product to specifications. In the event this element becomes applicable, the ISO/Management Analyst is responsible for ensuring this element is addressed.

Section 8 Measurement, Analysis, and Improvement

8.1 General

BRS plans and implements the monitoring, measurement, analysis and improvement needed to:

- Demonstrate conformity of the product.
- Ensure conformity of the QMS.
- Continually improve the effectiveness of the QMS.

This includes the determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 Monitoring and Measurement

8.2.1 Customer (Stakeholder) Satisfaction

BRS measures customer satisfaction in a number of ways:

- Utilizing periodic customer surveys and analysis of feedback data.
- Analyzing customer complaints per Procedure S26 Manage and Resolve Customer Feedback.
- Evaluating process performance standards and measures which are derived from customer requirements.

BRS uses the information generated from these sources in the review process to assess the level of satisfaction and determine the need for improvement actions per Procedure S23 Collect and Analyze Performance Data and Procedure S24 Conduct Reviews of System Performance.

8.2 Monitoring and Measurement, cont.

8.2.2 Internal Audits

BRS conducts internal audits at planned intervals to determine whether the QMS:

- Conforms to the planned arrangements (refer to Section 7.1).
- Conforms to the requirements of this International Standard and to the quality management system requirements established by the organization.
- Demonstrates effective implementation and maintenance.

An audit program is planned, taking into consideration the status and importance of the processes and areas to be audited and may encompass the results of previous audits. The audit criteria, scope, frequency and methods are defined. Selection of auditors and conduct of audits ensures objectivity and impartiality of the audit process. Auditors do not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (refer to Section 4.2.4) are documented in Procedure S25 Conduct Internal Audits.

Management responsible for the area audited ensures that actions are taken without unwarranted delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results (refer to Section 8.5.2).

8.2.3 Monitoring and Measurement of Process

BRS applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action are taken, as appropriate, to ensure conformity of the product.

8.2.4 Monitoring and Measurement of Product

BRS monitors and measures the characteristics of the product to verify that product requirements have been met. This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements (refer to Section 7.1).

8.2.4 Monitoring and Measurement of Product, cont.

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person(s) authorizing release of product (refer to Section 4.2.4).

Product release and delivery does not proceed until all the planned arrangements (refer to 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable, by the customer (stakeholder).

8.3 Control of Nonconforming Product

BRS ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are documented in Procedure S29 Manage Nonconformity.

BRS deals with nonconforming product by taking action to eliminate the detected nonconformity and/or taking action to preclude its original intended use or application.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained (refer to Section 4.2.4).

When nonconforming product is corrected, it is subject to re-verification to demonstrate conformity to the requirements.

When nonconforming product is detected after delivery or use has started, BRS takes action appropriate to the effects, or potential effects of the nonconformity.

8.4 Analysis of Data

BRS determines, collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the quality management system to evaluate where continual improvement of the effectiveness of the quality management system can be made. This includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to:

- a) Customer satisfaction (refer to 8.2.1).
- b) Conformity to product requirements (refer to 7.2.1).
- c) Characteristics and trends of process and products including opportunities for preventive action to BRS and suppliers.

8.5 Improvement

8.5.1 Continual Improvement

BRS continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management review.

8.5.2 Corrective Action

BRS has established and maintains a documented Procedure, S28 Perform Corrective and Preventive Actions, to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered. Procedure S28 Perform Corrective and Preventive Actions defines requirements for:

- a) Reviewing nonconformities (including customer comments).
- b) Determining the causes of nonconformities.
- c) Evaluating the need for action to ensure that nonconformities do not recur.
- d) Determining and implementing action needed.
- e) Records of the results of action taken (refer to Section 4.2.4).
- f) Reviewing corrective action taken.

8.5.3 Preventive Action

BRS has established and maintains a documented Procedure, S28 Perform Corrective and Preventive Actions, to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems. Procedure S28 Perform Corrective and Preventive Actions defines requirements for:

- a) Determining potential nonconformities and their causes.
- b) Evaluating the need for action to prevent occurrence of nonconformities.
- c) Determining and implementing action needed.
- d) Records of the results of action taken (refer to Section 4.2.4).
- e) Reviewing preventive action taken.

Appendix A Document History

Revision Number	Revision Date	Authorized By	Page Number	Description of Change
0	10/31/05	Steven Bennett	Entire Document	Initial Release
1	3/20/08	Steven Bennett	Entire Document	The Business Processes were updated to include processing functions in ePermits.
2	4/17/08	Steven Bennett	Page 8	Formatting modification for ERAD Biotechnologists in Figure 1. BRS Permits and Environmental Risk Analysis Teams.
			Page 9	Quality Policy applies to the Biotechnology Regulatory Services organization.

Appendix B Quality System Procedures
